COMMENTS ON THE NVAC SUBCOMMITTEE REPORT ON VACCINE RESOURCES AND FINANCING NEEDS

(The attached comments were mailed by Dr. Saldarini on December 11, 1989 to the NVAC Chair, Dr. Dandoy, after the full Committee discussed and approved the Subcommittee report.)

As revised, the proposed report of the National Vaccine Advisory Committee (NVAC) Subcommittee on Vaccine Resources and Financing Needs departs in three critical ways from earlier drafts circulated within the Subcommittee and the full NVAC:

First, the revised report does snot accept the proposition that appropriated funds for immunizations are limited in any way and advocates substantial additional funding for childhood immunizations.

Second, as a concomitant to the first revision, the report abandons any discussion of the imbalance which currently exists among states in the numbers of immunizations which are federally funded -- i.e., the imbalance in some states between public and private sector immunization activity.

Third, as part of a strategy to achieve complete federalization of immunizations, the revised report urges initiatives to reduce the price of vaccines.

These three revisions have been adopted with virtually no deliberation of discussion with int he Subcommittee, except for one meeting where the Chairman was not present. In addition, certain of the revisions are arguably inconsistent with information provided by Centers for Disease Control officials.

Likelihood of Additional Funding

The revised report states very forcefully "[t]here is no question but that substantially increased funds will have to be made available in the future for government purchase or a high percentage of childhood vaccines if we are to realize the full benefits of immunization, the most cost-beneficial procedures available to us in medical practice." This assertion simply fails to take into account the reality of the appropriations process int he current climate of concern for budget deficit reduction.

Champions of the childhood immunization program like Senator Bumpers have fought tirelessly for additional federal funds just to keep the number of publicly funded doses of vaccine constant in light of additional demands on resources, -- in the form of new vaccines, supplemental immunizations and somewhat increased prices. Notwithstanding that effort, there are no funds to increase the percentage of immunizations which are federally funded, nor are there likely to be in the future so long as Gramm-Rudman restrictions are in place. Continued complaints

about lack of funds run some risk of undermining the NVAC's credibility as well as alienating friends of the vaccine program in the Congress.

Since the NVAC is intended to provide policy guidance, not merely to the agency but also to Congress, there is substantially justification for a recommendation for greater funding, but as a matter of strategy, it should be accompanied by a "fall-back" position recognizing the difficulties which the Congress faces in increasing appropriations for individual programs. As the original draft report indicated, an appropriate fall-back position would involve examination of how efficiently the available funds are being used to reach children most in need of immunizations.

The revised report pays a great deal of attention to perceived problems of inadequate funding and excessive prices, but does not accept the fact that, at present, approximately half of the childhood immunizations in the country are provided without charge, having been purchased at sometimes artificially low prices through a federally-funded program. A free-vaccine program covering 50% of the nation's children goes well beyond the poverty level into solidly middle class children. There is no basis for arguing that additional free vaccine through federal purchased will necessarily improve the immunization rates among those where it is low -- in poor urban and rural areas. Indeed, there appears to be no correlation between improved immunization rates and the availability of free public sector vaccines.

Imbalance Between Public and Private Sector

It is assumed that no significant additional funds will be made available for childhood immunizations, and if immunization rates remain unacceptably low in certain populations, it is incumbent upon a rational immunization program to target the available resources in those areas most in need. Such an approach is not consistent with a laissez faire administration of the immunization program which allows some states to purchase low-cost, federally subsidized vaccine for all their children while other states, perhaps through ignorance or disorganization or other priorities, fail to take maximum advantage of the program. This problem should be addressed by NVAC, and in the revised report it is not.

Pricing of Vaccines

While we might all agree that in an ideal world all vaccines would be available at little or no cost, in fact our nation has been protected by a network of vaccines developed and marketing by private companies unable or unwilling to provide vaccines as a "loss leader." The NVAC should not embrace the notion of nationalizing vaccines without careful examination of the trade-off in terms of lost innovation. Virtually every major vaccine continues to be studied extensively for improvements in either safety or efficacy or both, and in most cases that study is being spearheaded by private industry. No research-based company will invest in a product where government price controls, as in other countries, threaten the ability to recover investment or to carry on the search for improved vaccines.

The specific suggestions of the revised draft seem particularly problematic. With regard to the suggestion of "[t]ransnational comparative pricing of vaccines," it is important to note that vaccine prices may be lower in other countries for a variety of reasons inapplicable to this country:

- Vaccines in other countries are not necessarily subject to the same safety and efficacy requirements as in the U.S. For example, World Health Organization potency standards for live oral poliovirus vaccines allow other countries does than under U.S. requirements. Moreover, the U.S. safety test for the same vaccine is more extensive and thus both more costly and most time-consuming.

- In many counties, such as Japan, pharmaceutical companies operate under rigorous state control. Because of the admitted cost-effectiveness of childhood vaccines, a premium is placed on the ready availability of vaccines as opposed to other pharmaceutical products. Accordingly, under the applicable regulatory scheme, vaccines are sold at an artificially low price which is counterbalanced by relatively high prices for drugs and other pharmaceutical.

- In other countries, manufacturers do not face the same product liability costs as in the United States. While the vaccine injury compensation system may alleviate this problem somewhat, there will remain some product liability exposure in an uncertain amount.

- Other countries do not have the same marketing costs as the United States, where private industry works extensively with pediatricians to keep them informed and supplied with an entire range of products.

- To the extent it exists in other countries, private industry does not make the same investment in research and development and does not therefore enjoy the same rate of innovation for improved vaccines and other vial products.

The recommendation of "[t]he Public Health Service should review its negotiating strategies to achieve lower prices" is puzzling since PHS has been quite successful in maintaining relatively low prices for vaccines which it purchases through federal appropriations. In every instance, there is a significant discount for federally purchased vaccines.

The revised report also recommends that "[r]esearch on new and improved production methods should be support to achieve less costly as well as improved vaccines. However, the revised report fails to take into account that such research itself may be costly and contribute to the price of existing vaccines.

Finally, the revised report refers to the 'usually beneficial effects of competition in stabilization of both supply and price." The experience in this country over the past decade does not support this concept. In fact, when there have been two or more manufacturers in a given market, there has been less stability because the competing manufacturers have no inventive to keep supplies beyond their anticipated share of the market. Thus, when one manufacturer experiences production problems, the others are unable to take up the slack. In contrast, when one manufacturer has the entire market, it recognizes an obligation to keep stocks of vaccine in excess of immediate needs. The sole manufacturer can rotate its stocks to avoid spoilage or other loss. In short, the process of planning efficiently is greatly facilitated for sole-source manufacturers. With regard to price, it would seem that there is no consistent pattern since both the least expensive childhood vaccine (OPV for the public sector) and the most expensive vaccine (MMR for the private sector are sold by single sources.

To summarize, no proof exists that the immunization status of children in this country would improve with greater federal funding of vaccine purchases. In addition, there is no real proof that the prices of childhood vaccines are excessive; in fact, the primary argument for these vaccines is their cost-effectiveness relative to other products or therapies. Clearly, the above comments represent the viewpoint of a vaccine manufacturer, but if the other members of NVAC wish to pursue the recommendations of the revised report, at least they should also consider the implications for vaccine improvement and innovation. Furthermore, consideration should be given to inviting congressional staff, the CDC and perhaps other Administration officials to express their views, perhaps off-the-record, on such issues as the practical likelihood of significantly enhanced appropriations, the relative utility of greater federal purchases of childhood vaccines, the best means of improving low immunization rates and the potential impact on research and development of more aggressive pricing policy by the federal government.